Regulatory improvements make Mexico an appealing destination for clinical trials outsourcing

Market forces and increasing regulatory oversight have placed substantial pressure on pharmaceutical companies to reduce drug development costs. Clinical trial outsourcing to destinations such as India and China has provided the opportunity to realize significant savings in drug development costs. At the same time, the old R&D model is changing from full in-house development at pharmaceutical companies to a new model driven by small to midsize biotechnology companies that provide promising drug candidates to weakening pipelines. For these up and coming and more agile biotechnology players, cost savings is quite important but, as the new pharmaceutical model relies on licensing and mergers and acquisitions (M&A), value creation is of utmost importance. As a result more and more biotechnology companies are seeking to take drug candidates as far into clinical development as possible.

But, does it make sense for a small to midsize biotechnology company that is limited to US operations to reach halfway across the world in search for the popular clinical outsourcing destination? In some cases, it does. Yet, for many others there is no need to go that far to realize the cost savings and more importantly the value creation promised by clinical trial outsourcing. Looking toward their neighbour south of the border, Mexico, could be as far as US biotech companies need to go.

Clinical trials in Mexico

Mexico stands out among many other clinical trial outsourcing destinations both for speed and cost savings.

The regulatory environment has improved significantly in recent years, particularly since the creation of the Mexican regulatory entity COFEPRIS. The total approval and set-up process for a clinical trial takes on average 3-4 months. This timeline is similar to that in European countries and much better than those normally seen in other Latin American countries that are often considered as important clinical trial outsourcing destinations. Argentina's average study approval time is six months while in Brazil the process may take nearly a year.

This improved timeline results from the considerable regulatory improvements seen in Mexico. However, there is still room for improvement. Even shorter study approval times are anticipated. Furthermore, in addition to offices in Costa Rica and Chile, the FDA opened a field office in Mexico City in 2010 allowing improved alignment between compliance of clinical trials performed in Mexico and regulatory expectations from the largest pharmaceutical market in the world, the US.

Patient recruitment and dropout rates

Mexico offers a large population of over 100 million, with more than a third of the population concentrated around three major metropolitan areas. Changes in lifestyle among the population in Mexico have resulted in an increased incidence of medical conditions commonly seen in developed countries, allowing for effective patient recruitment for diseases of greatest clinical and commercial interest. Recently, the COFEPRIS issued a list of therapeutic areas of priority for clinical investigation and among the list diabetes, cancer, cardiovascular disease and arthritis stand out as ailments commonly seen in the developed world. Furthermore, the majority of healthcare costs for this population are paid out-of-pocket. It is difficult for a significant portion of these patients to cover the costs associated with chronic disease and therefore willingness to participate in clinical trials is significant.

Moreover, strong doctor patient relationships facilitate the recruitment of treatment-naïve and eager patients, drastically increasing enrolment rates. Taken together, these factors support increased patient recruitment into trials. In addition to the potential for high patient recruitment rates, low dropout rates facilitate the speedy completion of clinical trials in Mexico. Greater recruitment speed and lower dropout rates expedite trial completion rates.

Trials in Mexico have a lower cost structure than those performed in the US and so cost savings can be quite significant. There are many drivers for these lower costs. For example, proximity to the US results in reasonable costs for research monitoring, fees for regulatory services are lower, and multiple academic

and private hospital and trial centres can be found concentrated in large urban areas. Furthermore, there is an ever increasing availability of principal investigators and the salaries or fees for professional services and medical procedures are also much lower than in the US. Finally, a favourable exchange rate to US dollars also helps drive down clinical research budgets.

Market access

In addition to lower costs and fast trial timelines, sponsor companies must keep in mind that the Mexican pharmaceutical market is sizeable and represents a significant opportunity on its own. In terms of sales, Mexico is the leading and most developed pharmaceutical market in Latin America and continually ranks as the eighth or ninth largest worldwide pharmaceutical market. Including Mexican sites as part of new drug development can increase a drug's visibility not only with key opinion leaders but also with regulators and other health authorities, the latter being a key stakeholder group in a country with a centralised, public healthcare system.

Other benefits

Geographical location is another easily identifiable advantage to trials performed in Mexico versus those performed in countries half a world away. Mexico shares time zones with the United States and its metro areas may be reached by short, three-to four-hour flights. This proximity can greatly facilitate administrative and operational oversight of outsourced trials and yield more successful trials. Central access to large numbers of potential patients and trial sites, along major metro areas, further simplifies clinical trial logistics. Additionally, import-export regulations are favourable for shipment of clinical trial materials.

In recent years, there has been a wave of increased spending in state of the art medical facilities that is giving rise to many additional alternatives to government-sponsored hospitals, where clinical trials have traditionally been run. For example, one of Mexico's largest hospital chains recently completed a $700 million building spree resulting in 15 new hospital facilities where the synergies between clinical trials and medical tourism are expected to be leveraged. The opportunity in these two industry segments has been further validated by recent investments from billionaire magnate Carlos Slim's financial group.

There are many well qualified, US-trained physicians in Mexico who could lead successful clinical trials. Moreover, training for clinical trial personnel, e.g. managers and coordinators, is also improving. The University of California in San Diego (UCSD), for example, has identified this pent-up demand for additional training for clinical trial personnel and developed a highly successful programme for clinical trial managers who come to San Diego for an intensive training course that includes topics such as Good Clinical Practice (GCP), ethics and the Institutional Review Board (IRB), trial administration and monitoring standards, as well as patient recruitment strategies.

Challenges

Although appealing, challenges and issues remain that should not be ignored when considering outsourcing clinical trials to Mexico, for example pharmacovigilance.

Further, interactions with Mexico's regulatory agencies can be hindered by the bureaucratic approach that is commonplace in government entities. The expectation of local thought leaders, however, is that there is an opportunity to improve in this regard and that COFEPRIS has identified the issue as one that stands in need of correction.

Partnerships

It is widely acknowledged that there is an absolute need to find a local partner to ensure successful completion of trials. It should be noted that, although many criteria must be considered when selecting a partner, the potential partner's previous clinical trials experience is a principal consideration. Sponsors need to thoroughly assess the partner's performance in selecting study sites and investigators, enrolling subjects, and meeting study deadlines. The partner's prior experience with trials in the particular therapeutic area to be studied is also a vital consideration. Other important questions that also need to be addressed during the partner selection process may include recruitment strategies, training and oversight of monitors, compliance standards, quality assurance and data handling. By carefully vetting previous performance and capabilities, sponsors should be able to select the right partner for their particular drug candidate with the proven ability to deal successfully with the regulatory, logistical and even cultural challenges of clinical trials in Mexico.

Outsourcing benefits for biotech

The new R&D pharmaceutical model relies heavily on biotechnology companies partnering with large pharmaceutical entities to fill their dwindling pipelines. In the process, small and medium-sized biotechnology companies are given the opportunity to capture a significant portion of the value created during drug development, particularly during clinical development stages. As biotech looks toward improving its licensing, partnering and acquisition deals, outsourcing of early stage clinical trials to Mexico can provide the needed cost savings and increased speed to effectively advance drug candidates through clinical development and better leverage their assets during the M&A process.

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